Atty. Dkt. No. 029488-0112

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Jay BUA

Title:

REDUCTION OF BREAST DENSITY WITH 4-HYDROXY

TAMOXIFEN

Appl. No.:

10/734,644

Filing Date:

12/15/2003

Examiner:

Not yet assigned

Art Unit:

1645

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner. An English-language counterpart of the foreign-language documents has not been provided. The absence of a translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 CFR §1.98 and MPEP§609).

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

NO 434 45

Stephen A. Bent

Attorney for Applicant

Registration No. 29,768

Date _____

FOLEY & LARDNER LLP Customer Number: 22428

Telephone:

(202) 672-5404

10/4/04

Facsimile:

(202) 672-5399

OCT 0 5 2004

MODIFIED PTO/SB/08 (08-00) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office: U.S. DEFARTIVE OF COMMENT.

Under the Paperwork Reduction Act of 1995, no persons are required respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: October 4, 2004

(use as many sheets as necessary)

Sheet of

Complete if Known			
Application Number	10/734,644		
Filing Date	12/15/2003		
First Named Inventor	Jay BUA		
Group Art Unit	1645		
Examiner Name	Not yet assigned		
Attorney Docket Number	029488-0112		

				U.S. PATENT DOCUMENTS	}	
Examiner Initials*		U.S. Patent Document			Date of Publication of	Pages, Columns, Lines, Where Relevant
	Cite No. ¹	Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Office ³ Number ⁴ Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	B1	WO 85/03228	Pierre MAUVAIS JARVIS et al.	8/1/1985		
	B2	WO 95/24187	Hexal-Pharma GMBH	9/14/1995		-

	NON PATENT LITERATURE DOCUMENTS				
Initials* Cite item (book, magazine, journal, serial, symposium, catalog,		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т ⁶		
	В3	International Search Report			
		Pierre MAUVAIS-JARVIS et al., "trans-4-Hydroxytamoxifen Concentration and Metabolism after Local Percutaneous Adminstration to Human Breast", Cancer Research Vol. 46, March 1986, pp. 1521-1525.			
	B5	F. KUTTENN et al., "Pricipe de l'adminstration percutanée des antiestrogènes en pathologie mammaire", Contracept. Fertil. Sex., 1991, Vol. 19, No. 2, pp. 165-171.			
normal human breast epithelial (HBE) cells in culture", Journal of Steroid Biochemistry and Molecular		Catherine MALET et al., "Effect of 4-hydroxytamoxifen isomers on growth and ultrastructural aspects of normal human breast epithelial (HBE) cells in culture", Journal of Steroid Biochemistry and Molecular Biology 82, (2002), pp. 289-296.			
		Charlotte ATKINSON et al., "Mammographic Patterns as a Predictive Biomarker of Breast Cancer Risk: Effect of Tamoxifen", Cancer Epidemiology, Biomarkers and Prevention Vol. 8, October 1999, pp. 863-866.			

4		,	
	Examiner Signature	Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.